

MAR 15 2006

K060328

**510K) SUMMARY****DATE**

February 7, 2006

**PRODUCT, CLASSIFICATION NAME**

Trade name: Planmeca Promax 3D

Common name: Panoramic/Tomography x-ray system

Classification: 76 EHD, Class II

Regulation number: 872.1800

**MANUFACTURER**

Planmeca Oy

Asentajankatu 6

FI-00880 Helsinki, Finland

Phone: +358 20 7795 500

Fax: +358 20 7795 396

Contact person: Lars Moring

**UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)**

Planmeca USA Inc.

100 North Gary Avenue, Suite A

Roselle, IL 60172

Phone: (630) 529 2300

Fax: (630) 529 1929

Contact person : Bob Pienkowski

**INTENDED USE**

Planmeca Promax 3D, is a three dimensional Cone Beam Computed Tomography (CBCT) x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals.

**PRODUCT DESCRIPTION**

The Planmeca Promax 3D is in principle a conventional digital panoramic x-ray system with three-dimensional Cone Beam Computed Tomography (CBCT) system add on. The product rotates around the patient and takes still images with a flat panel sensor synchronized to x-ray generator pulsing. A 3D reconstruction engine calculates the cylindrical 3-dimensional volume image, which then is viewed in 3D viewing stations.

**PLANMECA**

ENCLOSURE 12

P. 12-2

**SUBSTANTIAL EQUIVALENCE**

We consider this product modification including a new 3D CBCT x-ray system to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

# K052587 3D Accu-i-tomo XYZ Slice View Tomograph

The comparison of characteristics supports substantial equivalence. Planmeca Promax 3D is as safe and effective as the predicate device.

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**

**MAR 15 2006**

Mr. Lars Moring  
Regulatory Affairs Manager  
Planmeca Oy  
Asentajankatu 6  
FI-00880 Helsinki  
FINLAND

Re: K060328  
Trade/Device Name: Planmeca Promax 3D  
Regulation Number: 21 CFR 872.1800  
Regulation Name: Extraoral source  
x-ray system  
Regulatory Class: II  
Product Code: MUH  
Dated: February 7, 2006  
Received: February 9, 2006

Dear Mr. Moring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

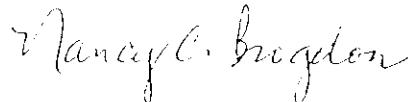
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): **K060328**

Device Name: **Planmeca Promax 3D**

### Indications For Use:

Planmeca Promax 3D, is a three dimensional Cone Beam Computed Tomography (CBCT) x-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified professionals.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

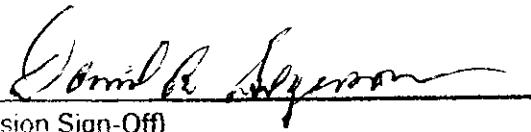
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K060328

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